FOLLOW-UP ALERT FROM THE CDC AND THE CAP: Potentially hazardous material contained in CAP 2005 Proficiency Testing Surveys: VR1A-2005, VR4-A-02005 and XL-C-2005

This alert is a follow-up to the fax that was sent by the College of American Pathologists (CAP) on Friday, April 8, 2005 to laboratories that received one of the following proficiency testing products: 2005 Virology Culture Survey, Specimen VR1-05; 2005 Virology Antigen Survey, Specimen VR4-02 or EXCEL Viral Antigen Detection Module M21, Specimens XV-04 and XV-05.

The College was notified by the Centers for Disease Control and Prevention (CDC) on April 8, 2005, that a specimen in these Surveys was an Influenza A subtype H2N2, which is currently being considered for reclassification by the CDC and the National Institutes of Health (NIH) from a Biosafey Level 2 to a Biosafety Level 3.

That same day, the College sent a fax to all participating laboratories asking them to immediately destroy samples containing this virus. This action was deemed prudent because of the length of time since this subtype circulated among humans and the consequent waning of immunity and corresponding increase in susceptibility of humans. Thus, working with H2N2 viruses could theoretically pose a health risk to laboratory staff born after 1968. A representative H2N2 virus is not contained in current trivalent influenza vaccines.

As of today, there have been no reports of H2N2 infections among laboratory workers handling the H2N2 samples from CAP.

Laboratory-associated infections have not been routinely documented in the literature, but informal accounts and published reports indicate that such infections have occurred in the past. These infections occurred when influenza viruses showing marked antigenic shift or antigenic drift were worked on in the laboratory under less stringent biosafety conditions than are recommended today and especially during work done in the past with experimentally or naturally infected animals.

Biosafety Level 2 recommendations and OSHA requirements focus on the prevention of percutaneous and mucous membrane exposures to clinical material (http://www.cdc.gov/od/ohs/biosfty/bmbl/bmbl-1.htm). Biological safety cabinets must be used for the processing of clinical specimens when the nature of the test requested or other information suggests the likely presence of an agent readily transmissible by infectious aerosols (e.g., influenza viruses). The proper use of biological safety cabinets, along with use of recommended PPE, greatly reduces the chances of laboratory-acquired influenza infections.

Up to the present time, Biosafety Level 2 containment has been recommended in most countries for use of human influenza isolates that are or have been in wide circulation in human populations (human influenza A/H1N1, H2N2 and H3N2 subtype viruses). **Given these recommendations it is expected that the likelihood of infection of a laboratorian is low if proper Biosafety Level 2 precautions are used.**

Out of an abundance of caution due to potential and theoretical risks currently associated with working with H2N2 viruses, the CDC and the CAP recommend the following:

1. Immediately autoclave, incinerate and treat as hazardous all materials you may have retained or derived from the following proficiency specimens:
    a. Specimen VR1-05 contained in 2005 VR1 Virology Culture Survey.
    b. Specimen VR4-02 contained in 2005 VR4 Virology Antigen Survey.
    c. Specimens XV-04 and XV-05 contained in 2005 EXCEL M21 Viral Antigen Module.

    Treat them in a manner consistent with CDC and FDA recommendations and OSHA blood borne pathogen rules (http://www.cdc.gov/od/ohs/biosfty/bmbl/bmbl-1.htm)
2. Confirm **within 24 hours** of specimen destruction to the College of American Pathologists by fax that the above mentioned proficiency specimens and all derivatives have been destroyed.
3. Monitor laboratory staff who have worked with 2005 Surveys and EXCEL proficiency specimens VR1-05, VR4-02, XV-04 and XV-05 for influenza-like illness (fever of >100^{o}F and cough or sore throat) and follow up with laboratory testing to determine the etiology of infection. Influenza A infections that are detected in laboratory staff who have worked with these specimens should be reported immediately to national public health authorities and specimens should be retained for testing by national or international reference laboratories.
4. Immediately pass this information on to any laboratories to which you may have sent 2005 Survey or EXCEL proficiency testing specimens VR1-05, VR4-02, XV-04 or XV-05 and report this action to the College of American Pathologists by e-mail or fax.

The CDC and NIH along with a panel of influenza experts are in the process of drafting changes to the Biosafety and Microbiological and Biomedical Laboratories 5th Edition that may designate influenza viruses of the H2N2 subtype as Biosafety Level (BSL) 3 agents.

Future CAP Viral Culture Surveys will contain only influenza A H1N1 or H3N2 strains deemed appropriate for Biosafety Containment Level 2 until a time when the circulation of influenza A virus subtypes changes.

If you have any questions, please contact the CAP Customer Contact Center at 1-800-323-4040, Option 1. Thank you for your cooperation in this matter.